Nitrile disposable Gloves | POWDER-FREE

MEDCARE
Medical protection

QUALITY STANDARDS

- Conforms to EN455, EN 420,EN374-1, EN374-2:3019 and EN ISO 21420:2020
- Manufactured under QSR (GMP), ISO 9001:2015 Quality Management System

GLOVE SIZES

- Small, Medium, Large, Extra-Large
- Size of gloves shall be marked in the check box on the shipping carton with black ink

PRODUCT SPECIFICATIONS

Type	Powdered & Powder-Free, Non-sterile
Material	100% Nitrile Latex-Free
Colour	Blue
Design & Features	Powedered-Free: Polymer coated or online single chlorinated, offline double chlorinated, ambidextrous, finger textured or palm textured surface, beaded cuff
Storage	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight
Shelf-Life	3 years from the date of manufacturing

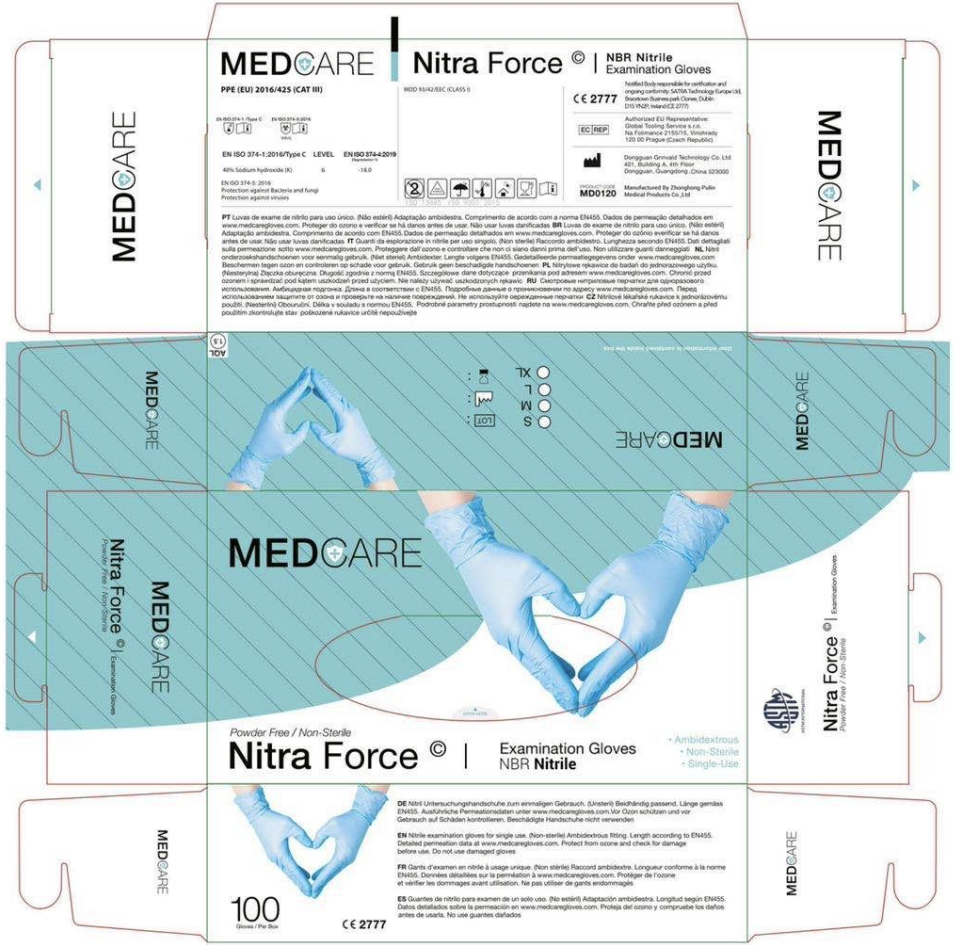
PRODUCT SPECIFICATIONS

Standard	EN 455		
Length (mm)	Min 230, Min 240, 300 ± 10	Min 220 (S) Min 230 (M, L, XL)	Min 240
Palm Width (mm)			
• S	84 ± 3	80 ± 10	80 ± 10
• M	94 ± 3	95 ± 10	95 ± 10
• L	105 ± 3	110 ± 10	110 ± 10
• XL	113 ± 3	120 ± 10	2:110
Thickness: Single Wall (mm)			
• Finger	Min 0.08 -0.12	Min 0.08	**N/A**
• Palm	Min 0-05 -0.12	Min 0.05	**N/A**

PHYSICAL PROPERTIES

Property	EN 455	
Tensile Strength (MPa)		
• Before Aging	14	N/A
• After Aging	14	N/A
Elongation at Break(%)		
• Before Aging • After Aging	Min 500 Min 400	N/A N/A
Median Force at Break (N)		
• Before Aging	N/A	Min 6
• After Aging	N/A	Min 6

MEDCARE
Medical protection



2020

CERTIFICATE OF REGISTRATION

This certifies that:

DONGGUAN GRINVALD TECHNOLOGY CO. LTD
401, Building #3, No 4 Of Guangming New Village 2 Road
Dongcheng
Dongguan City Guangdong, CN 523000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10071856**
DUNS No.:	**55-453-3470**
Device Classification Name:	**POLYMER PATIENT EXAMINATION GLOVE**
Product Code:	**LZA**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: July 13, 2020

Products

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Precisely Right.

Report No.:	242122000-01a	Page 1 of 3
Client:	Dongguan Grinvald Technology Co., Ltd.	
Contact Information:	401 Building A 4th Floor, Dongguan Guangdong China 523000	
Identification/ Model No(s):	MEDCARE NITRILE EXAMINATION GLOVES	
Sample Receiving date:	2020-08-05	
Sample Resubmitted date:	2020-08-20	
Testing Period:	2020-08-05 to 2020-08-27	
Delivery condition:	*Apparent good, Samples tested as received*	

Test Specification:	*Test result:*
1. EN 455-1: 2000: Requirements for freedom from holes	PASS

Other Information provided by client:
Grade: Examination Gloves Powder Free
Manufacture: Dongguan Grinvald Technology Co., Ltd.
Country of Origin: China

The report 242122000-01a supersede report 242122000-01 (Revised Identification/Model No.(S))

For and on behalf of
TÜV Rheinland Thailand Ltd.

2020-09-01	Wilawan Sriphrom / Manager
Date	*Name/Position*

Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned Test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

TÜV Rheinland Thailand Ltd. · Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1, Soi Chalongkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com · Web:www.tuv.com

Test Report No.: 242122000-01a

Sampling Information:
Inspection Method: No inspection
Inspection level: N/A
AQL: N/A
Sample size: N/A

Material list:

Material No.	Material	Color	Location
M001	Nitrile Gloves	Blue	Refer to photo

Freedom from holes

Test method: With reference to EN 455-1: 2000

Test result:

Material No.	Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
M001	M	200 pcs.	1	Pass

Remark:

1. All samples were selected and supplied by the client.
2. The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455-1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. with reference to table, the result can be judged as above AQL 0.65.

Stage No.	Cumulative no. tested	Accept	Reject
First	50	0	4
Second	100	1	6
Third	150	3	8
Fourth	200	5	9
Fifth	250	9	19

Products

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Test Report No.: 242122000-01a

Sample photo

-END-

TÜV Rheinland Thailand Ltd. · Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1, Soi Chalongkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com · Web:www.tuv.com

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

Ⅱ. The content of this part is extracted from the test report number GZHL2007037331OT.
1. SGS Ref No.: CAN20-117986

Test Requested	Result
Entry 63 of Commission Regulation (EU) 2015/628 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Lead and its compounds	PASS
Entry 23 of Commission Regulation (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Cadmium and its compounds	PASS
Entry 50 of Commission Regulation (EU) 2015/326 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Polycyclic Aromatic Hydrocarbons (PAHs)	PASS
Entry 51 of Commission Regulation (EU) 2018/2005 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Phthalates	PASS
European Regulation POPs (EU) 2019/1021 - Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)	PASS

Test Results :

Test Part Description :

SGS Sample ID	Description
CAN20-117986.001	Blue soft plastic(glove)

Remarks :

(1) 1 mg/kg = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)
(4) "-" = Not Regulated

Entry 63 of Commission Regulation (EU) 2015/628 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Lead and its compounds

Test Method : SGS In-house method (GZTC CHEM-TOP-004-01, with reference to EPA 3052:1996), analysis was performed by ICP-OES.

Test Item(s)	Limit	Unit	MDL	*001*
Lead (Pb)	500	mg/kg	2	ND

Entry 23 of Regulation (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Cadmium and its compounds

Test Method : SGS In-house method (GZTC CHEM-TOP-004-01, with reference to US EPA Method 3052:1996), analysis was performed by ICP-OES.

Test Item(s)	CAS NO.	Limit	Unit	MDL	*001*
Cadmium (Cd)	7440-43-9	0.01	%(w/w)	0.0005	ND

Entry 50 of Regulation(EU) 2015/326 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Polycyclic Aromatic Hydrocarbons (PAHs)

Test Method : With reference to AfPS GS 2019:01 PAK, analysis was performed by GC-MS.

Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Benzo(a)anthracene(BaA)	56-55-3	1.0	mg/kg	0.1	ND
Chrysene(CHR)	218-01-9	1.0	mg/kg	0.1	ND

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198 Kezhu Road,Scientech Park Guangzhou Economic & Technology Development District,Guangzhou,China 510663 t (86-20) 82155555 f (86-20) 82075191 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075191 e sgs.china@sgs.com
Member of the SGS Group (SGS SA)

WORK REQUESTED

Samples described as Nitrile examination gloves, powder free, colour blue, referenced MD0120. Size S (6), M (7), L (8) were received by SATRA on 22 July 2020 for testing in accordance with EN ISO 21420: 2020 and EN 374-2: 2014.

SAMPLE SUBMITTED

Samples described as Nitrile examination gloves, powder free, colour blue, referenced MD0120. Size S (6), M (7), L (8).

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves
EN 374-2: 2014 Clause 7.2 – Air leak
EN 374-2: 2014 Clause 7.3 – Water leak

CONCLUSION

The samples described as Nitrile examination gloves, powder free, colour blue, referenced MD0120. Size S (6), M (7), L (8) were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN ISO 21420: 2020 Clause 4.2* – Pass PAHs, DMFa and pH value
EN 374-2: 2014 Clause 7.2* – Pass
EN 374-2: 2014 Clause 7.3 – Pass

All tests marked * in this technical report were subcontracted to test facilities accredited to ISO/IEC 17025: 2017 by CNAS.

Detailed results are included on the following page(s)

Testing

Testing was carried out in accordance with EN 374-2: 2014

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2)°C and (50±5)% relative humidity.

Requirements

Requirements for EN 374-2: 2014

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

EN 374-2: 2014 Test Results

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used	3.0 kPa	NA	Pass
	Sample size	Leaks		
	6	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
7.3 Water leak test	Sample size	Leaks	NA	Pass
	6	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		

***** End of Report *****

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 9, 2016

Zhonghong Pulin Medical Products Co., Ltd.
c/o Mr. Chu Xiaoan
Room 1606 Bldg. 1, Jianxiang Yuan No. 209
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re: K152712
Trade/Device Name: Nitrile Powder Free Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: January 28, 2016
Received: February 1, 2016

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number *(if known)*
K152712

Device Name
Nitrile Powder Free Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*
Nitrile Powder Free Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6593 EF

	powder	2mg of residual powder	
Materials used to fabricate the devices	Nitrile	Nitrile	Substantially equivalent
Dusting or Donning Powder: name	PU	Polyurethane	Substantially equivalent
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Substantially equivalent
Single Patient Use	Single Patient Use	Single Patient Use	Substantially equivalent
Biocompatibility	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006 Under the conditions of the study, not an irritant and under conditions of the study, not a sensitizer.	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10: Third Edition 2010-08-01. Under the conditions of the study, not an irritant and under conditions of the study, not a sensitizer.	Substantially equivalent
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	Substantially equivalent

10.0 Substantial Equivalence Comparison:

It can be concluded that the Nitrile Powder Free Patient Examination Gloves, Blue Color meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims.

It can be concluded that the Nitrile Powder Free Patient Examination Gloves, Blue Color is as safe, as effective, and performs as well as the predicate device, Nitrile Powder Free Patient Examination Gloves, Blue Color, Tangshan Zhonghong Pulin Plastic Co., Ltd.. K120970.


MEDCARE
Powder Free / Non-Sterile
Nitra Force ©
Nitrile Examination Gloves
• Ambidextrous
• Non-Sterile
• Single-Use


MEDCARE
protection
XS
S
M
L
XL
Distributed by:
Global Tooling Service s.r.o
Na Folimance 2155/15,
12000 Prague, Czechia
MADE IN CHINA


MEDCARE
Nitra Force ©
Nitrile Examination Gloves
MDD 93/42/EEC (Class I),EN 455
Authorized EU Representative:
Global Tooling Service s.r.o.
Na Folimance 2155/15, Vinohrady 120 00 Prague
(Czech Republic)
Dongguan Grinvald Technology Co. Ltd
401, Building #3, No 4 of Guangming
New Village 2 Road Dongcheng
Dongguan City, Guangdong Province, China 523000
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